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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:

10/569,957

Group Art Unit:

3777

Filing Date:

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Examiner:

Hien Ngoc Nguyen

Applicant:

Kristine FUIMAONO

Title:

METHOD AND DEVICE FOR VISUALLY SUPPORTING AN

ELECTROPHYSIOLOGICAL USE OF A CATHETER IN THE HEART

Attorney Docket:

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REASONS FOR PRE-APPEAL BRIEF REQUEST FOR REVIEW

Sir:

Concurrent with the filing of a Notice of Appeal and a Request for Pre-Appeal Review, the following remarks are submitted in connection with the above-identified patent application.

REJECTIONS FOR WHICH PRE-APPEAL BRIEF REVIEW IS REQUESTED

Claims 1-3, 6, 8-15, 17-18 and 21-23 are pending.

Claims 15, 22, 1-3, 9-10, 14, and 18 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Packer et al. (US 6,556,695), hereinafter "Packer," in view of Leiper (US 6,128,002) hereinafter "Leiper," and further in view of Rose (US 2002/0176608), hereinafter "Rose," and Hemler et al. (A System for Multimodality Image Fusion), hereinafter "Hemler." Claims 17, 21, and 6 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Packer in view of Leiper and further in view of Rose, Hemler, and Williams et al. (DE 19953308-A1), hereinafter "Williams." Claims 23 and 13 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Packer in view of Leiper and further in view of Rose, Hemler and Hughes et al. (US 7,233,340), hereinafter "Hughes." Claim 8 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Packer in view of Rose, Hemler, and Schweikard et al. (US 6,144,875), hereinafter "Schweikard." Claim 11 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Packer in view of Leiper and further in view of Leiper and further in view of Leiper and further in view of Rose, Hemler, and Schweikard et al. (US 6,144,875), hereinafter "Schweikard." Claim 11 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Packer in view of Leiper and further in view of Rose, Hemler, and Krishnan (US 6,771,262), hereinafter "Krishnan."

Claim 12 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Packer in view of Leiper and further in view of Rose, Hemler, and Massaro et al. (US 2002/0087329), hereinafter "Massaro."

ARGUMENTS

The Examiner continues to reject independent claims 1 and 15 based on the combination of the teachings of Packer, Leiper, Rose and Hemler.

It is alleged in the Office Action that FIG. 1, col. 2, lines 14-60, col. 3, lines 51-67 and col. 5, lines 45-62 of Packer teach an interface for "electroanatomical 3D mapping data and 3D image data," as recited in independent claim 15.

However, Applicants submit that Packer fails to disclose or even suggest any "electroanatomical 3D mapping data," as required by claim 15. FIG. 1 of Packer merely illustrates a MRI apparatus. Col. 3, lines 51-67 of Packer relate to the imaging modality for producing the high resolution model (CT, MRI, ultrasound). Col. 2, lines 14-60 of Packer disclose acquiring image data of the subject anatomy and reconstructing an image which is a high resolution model of the subject anatomy; performing a medical procedure in which the subject anatomy is imaged in real-time by acquiring low resolution images at a high frame rate; registering the high resolution model of the subject anatomy with each acquired low resolution image; and displaying images of the registered high resolution model of the anatomy. As is understood, the cited sections of Packer do not disclose or even suggest any "3D mapping data," as recited in independent claim 15.

In addition, the Examiner provides a generic statement, on pages 2-3 of the Office Action, that "Packer discloses a system that perform [sic] an imaging method therefore the system must have at least one input interface for electroanatomical 3D mapping data and 3D image data." However, as demonstrated above, Packer acquires low resolution images, not 3D images.

Moreover, the Examiner provides that Packer "must" have an interface for 3D mapping and image data. However, in establishing that an element is inherent in a reference, the missing element must be necessarily present in the apparatus described in the reference(s) such that the presence of these elements would be recognizable by persons of ordinary skill. *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999). The Examiner has not established that an interface for 3D mapping and image data is inherent to the disclosure of Packer because another interface can be used. For example, Packer even goes as far to disclose an interface for low resolution images, but does not disclose an interface for 3D mapping data and 3D image data.

Leiper, Rose and Hemler fail to cure the deficiencies of Packer described above.

Therefore, Packer, Leiper, Rose and Hemler fail to disclose or suggest an interface for "electroanatomical 3D mapping data and 3D image data," as recited in claim 15.

It is further alleged in the Office Action at page 3 that col. 6, lines 14-45 and col. 7, lines 7-23 of Packer disclose "an extraction module, designed to extract at least significant portions of an area to be treated by segmenting the 3D image data to obtain a 3D surface profile," as recited in independent claim 15. (Emphasis added.)

However, the cited sections of Packer are directed to the process of rendering acquired 3D surfaces on a 2D display. Further, these sections of Packer are directed to processing the acquired 3D image data into a 4D model from which 3D heart wall surfaces can be rendered. This process of rendering acquired 3d surfaces involves segmenting of the heart walls and tiling of the surfaces of the segmented heart wall images. However, no "3D surface profile" is extracted. Packer fails to teach or even suggest "a 3D surface profile," as recited in independent claim 1.

Moreover, the Examiner admits that Packer does not explicitly teach "3D surface profile," as required by claim 15, and relies on the teachings of Rose to overcome the noted deficiencies of Packer.

Particularly, the Examiner alleges that paragraphs [0005-0007] of Rose teach "surface matching the 3D surface profile," as recited in independent claim 15.

Rose is directed to a non-contact surface profiling method using light. Rose focuses primarily upon road surfaces. However, as per Rose, the discussion applies equally to any surface intended for vehicular traffic. According to Rose, these surfaces include, but are not limited to, highways, roads, ramps, parking, and service areas for ground vehicles (trucks, cars, busses, etc.), runways, taxiways, parking aprons, and hangar floors for aircraft, and tracks and roadbeds for railroads. The terms "road" and "road surface," as used herein, refer specifically to "a road" and "a surface of a road," respectively, and refer generally to "a way or course for ground, air, or rail vehicles" and "a surface of a way or course," respectively. The sections of Rose cited by the Examiner are reproduced below.

[0005] In the industry, <u>road condition is measured by profiling</u>. Profiling is the obtaining of a profile or series of profiles of the road surface. A profile is substantially a cross-sectional view of the surface of the road. A profile depicts the contours of the road, thereby demonstrating the form, wear, and irregularities of the road surface.

[0006] A transverse profile is a cross-sectional view of the road surface or a portion thereof taken substantially perpendicular to the direction of travel. A transverse profile may be used to depict rutting, potholes, scaling, chipping, and edge damage of the road surface over time.

[0007] A longitudinal profile is a cross-sectional view taken substantially

in the direction of travel. A longitudinal profile may be used to depict the grade, waviness, and roughness of the road surface. Longitudinal profiles may be used to monitor the wear of the road surface over time to facilitate maintenance planning.

(Emphasis added.)

Absolutely, nowhere in Rose is it mentioned that the techniques disclosed therein can be used in the field of medical imaging. Nowhere in Rose is it disclosed that the device disclosed therein can be modified to image living organisms, or, rather, extract 3D surface profiles of organs of living organisms.

The Examiner's rejection of the claims is based on improper hindsight reconstruction gleaned from viewing Applicants' Specification and reading the of claims, and not on a reason with some rational underpinnings for combining Packer and Rose. Rose does not appear to be interested in the 3D surface profiling of organs of living organisms. The Examiner has provided no evidence or reasoning that Rose appears to be interested in producing 3D surface profiles of organs of living organisms.

Accordingly, the combination¹ of Packer, Leiper, Helmer and Rose is not an obvious combination of prior art elements or a simple substitution of one known element for another, leading to predictable results, or any other indicator of potential obviousness. Rather the extensive amount of modification needed is suggested nowhere in the cited references or by the Examiner, and is born from use of impermissible hindsight reconstruction in view of the Applicants' Specification and reading of the claims. (See, for example, *Ex parte Kobayashi*, Appeal 2009-000884, Application No. 10/031,282).

Leiper and Hemler fail to cure the deficiencies of Packer and Rose described above.

Therefore, Packer, Leiper, Rose and Hemler fail to disclose or suggest "surface matching the 3D surface profile from the 3D image data to a 3D surface profile from the 3D mapping data," as recited in claim 15.

Applicants submit that for all the above reasons, the alleged combination of Packer and Rose fails to render the limitation of independent claim 15, and the somewhat similar features recited in independent claim 1 obvious to one of ordinary skills in the art.

¹ On numerous past occasions, the Examiner has indicated that his rejection is not based on the literal incorporation of the device/method of Rose in the device/method of Packer, but is based on the modification of the Packer device/method using the teachings of Rose of obtaining 3D surface profile.

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Claims 2-3, 9-10 and 14 are patentable based at least on their dependency on claim 1. Claims 18 and 22 are patentable at least by virtue of its dependency on claim 15.

With regards to claims 6, 8, 11-13, 17, 21 and 23, the Examiner correctly acknowledges that the features of these claims are absent from Packer, Leiper, Rose and Hemler, but alleges that these features are taught by Williams, Hughes, Schweikard, Krishnan or Massaro thereby rendering claims 6, 8, 11-13, 17, 21 and 23 obvious to one of ordinary skill at the time of the invention. Even assuming *arguendo* that the features of these claims are taught by Williams, Hughes, Schweikard, Krishnan or Massaro (which Applicants do not admit) and that Williams, Hughes, Schweikard, Krishnan or Massaro could be properly combined with Packer, Leiper, Rose and Hemler (which Applicants do not admit), Packer, Leiper, Rose, Hemler and Williams, Hughes, Schweikard, Krishnan or Massaro are still deficient with respect to the above-described features of claims 15 and 1. Thus, even in combination, Packer, Leiper, Rose, Hemler and Williams, Hughes, Schweikard, Krishnan or Massaro fail to render claims 6, 8, 11-13, 17, 21 and 23 obvious.

In light of the above, Applicants respectfully request the rejection of claims 1-3, 6, 8-15, 17-18 and 21-23 be withdrawn.

CONCLUSION

In view of the remarks, reconsideration and withdrawal of the current rejections in connection with the present application is earnestly solicited.

Should there be any outstanding matters that need to be resolved in the present application, the Pre-Appeal Brief Review Panel is respectfully requested to contact the undersigned at the telephone number below. If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 08-0750 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

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